REMARKS

Prior to the present amendment claims 21 to 23 and 25 to 29 were pending. Claims 25, 28 and 29 have been canceled herein, and new claims 30 to 32 have been added. Claims 21 to 23 and 30 to 32 are withdrawn from consideration. Claims 26 and 27 are presently under examination and have been indicated to be allowable.

Regarding the new claims

New claims 30 and 31 are directed to a diagnostic method that relies on a binding agent which is a monoclonal or polyclonal antibody, respectively. These new claims are supported throughout the specification, for example, at page 21, lines 10-13, which indicates that an antibody can be a monoclonal or polyclonal antibody.

New claim 32 is directed to a diagnostic method in which the sample is a serum sample. This new claim is supported throughout the specification, for example, at page 23, lines 19-31, which discloses methods of diagnosing or predicting susceptibility to a prostate neoplastic condition in an individual by measuring a test expression level of PAMP in a sample and further discloses that samples include serum samples.

As set forth above, the new claims are supported in the specification and do not add new matter. Applicant therefore respectfully requests that the Examiner enter the new claims.

Regarding the written description rejection

The rejection of claims 28 and 29 under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description is respectfully traversed. The Office Action asserts that the claims read on variants of SEQ ID NO: 2, including variants having any type of amino acid substitution besides conservative substitutions. The Office Action further asserts that there is no disclosure of common structural or functional attributes that identify the claimed variants.

Applicant maintains, as argued previously, that the specification provides written description sufficient to convey to one skilled in the art that Applicant had possession of the invention of claims 28 and 29, directed to isolated PAMP polypeptides having at least 90% or 95% amino acid identity with at least 350 residues of SEQ ID NO: 2, including residues 1075 to 1382 of SEQ ID NO: 2. The specification provides guidance, for example, by providing at least 350 residues of SEQ ID NO: 2, as shown in Figure 1, and by teaching structural attributes common to the PAMP polypeptides of claims 28 or 29. Structural attributes are provided by the disclosure of SEQ ID NO: 2 and the teaching that the PAMP polypeptide has at least 90% or 95% sequence identity with SEQ ID NO: 2 (see page 19, lines 12-15). Thus, the PAMP polypeptides of claim 28 are united by the common structural attribute of sharing at least 9 out of 10 residues in common with the specified portion of SEQ ID NO: 2. Similarly, the PAMP polypeptides of claim 29 are united by the common structural attribute of sharing at least 19 out of 20 residues in common with the specified portion of SEQ ID NO: 2. In view

of the above, it would have been clear to the skilled person that Applicant was in possession of the claimed invention at the time the application was filed.

Nevertheless, in order to further prosecution of the subject application, claims 28 and 29 have been canceled herein without prejudice to Applicant pursuing these claims in an continuation application claiming the benefit of priority of the subject application.

Applicant therefore respectfully requests that the Examiner reconsider and remove the written description rejection of claims 28 and 29.

Regarding the enablement rejection

The rejection of claims 28 and 29 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement is respectfully traversed. The Office Action asserts that, while the specification discloses how many amino acids can be substituted, deleted or added, the specification does not disclose which amino acids in which positions within the 350 amino acids of SEQ ID NO: 2 can be substituted, deleted or added.

For the reasons of record, Applicant maintains that the specification enables the full scope of the invention of claims 28 and 29. Applicant has previously argued that the claimed invention has a well established utility, that of preparing anti-PAMP antibodies for identification of prostate tissue. Furthermore, the specification provides guidance regarding making and using PAMP polypeptides as immunogens. Essentially,

guidance regarding making polypeptides related to SEQ ID NO: 2 is provided in Figure 1, which discloses the amino acid sequence SEQ ID NO: 2 and the encoding nucleic acid sequence SEQ ID NO: 1; guidance regarding using a PAMP polypeptide as an immunogen for preparation of monoclonal and polyclonal antibodies is provided in the specification at pages 21 to 23. (See, for example, page 21, line 31, to page 22, line 4; page 22, lines 16-24; and page 22, line 25, to page 23, line 17). Because only routine work would have been required to make and use the polypeptides of claims 28 and 29 as immunogens, the specification enables the invention of claims 28 and 29.

Applicant has nevertheless canceled claims 28 and 29 herein without prejudice to Applicant pursuing these claims in another application claiming the benefit of priority of the subject application. In view of the above remarks, Applicants respectfully requests that the enablement rejection under 35 U.S.C. § 112, first paragraph, be removed.

Regarding the withdrawn claims

Applicant respectfully requests that the Examiner consider rejoining withdrawn claims 21 to 23 and 30 to 32 with elected claims 26 and 27. Applicant submits that there would not be a serious burden on the Examiner to examine diagnostic methods which involve determining an expression level of a PAMP polypeptide (claims 21 to 23 and 30 to 32) together with claims 26 and 27, directed to isolated PAMP polypeptides. In particular, the PAMP polypeptide subject matter of Group II, while patentably distinct from the diagnostic methods of Group

IV, is related to these diagnostic methods and no serious burden is imposed on the Examiner to search and examine both groups of claims. Furthermore, Applicant asserts that a thorough search of the subject matter of Group II has likely resulted in discovery of any art relevant to the diagnostic method claims of Group IV. Thus, searching and examining both groups of claims together will avoid a duplicative effort on the part of the Patent and Trademark Office.

In sum, it is respectfully requested that the Examiner reconsider and rejoin claims 21 to 23 and 30 to 32 with the elected claims under examination.

CONCLUSION

Applicant respectfully requests that the Examiner consider the amendments and remarks herein above. The Examiner is invited to call the undersigned agent or Cathryn Campbell if there are any questions.

Respectfully submitted,

Date: February 11, 2004

Andrea L. Gashler
Registration No. 41,029
Telephone: (858) 535-9001
Facsimile: (858) 535-8949

McDERMOTT, WILL & EMERY
4370 La Jolla Village Drive
Suite 700
San Diego, California 92122